UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 19 2009

UNITED STATES PATENT AND TRADEMARK OFFICE
MAILSTOP HATCH-WAXMAN PTE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Gregory T. Lowen
Morgan Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004

In re: Patent Term Extension
Application for.
U.S. Patent No. 4,911,932

DENIAL OF PATENT TERM EXTENSION APPLICATION FOR U.S. PATENT NO. 4,911,932

This is in response to the application for extension of the patent term of U.S. Patent No. 4,911,932 (the '932 patent) under 35 U.S.C. § 156, which was filed in the United States Patent and Trademark Office ("USPTO") on April 5, 2006. The patent term extension application ("PTE application") was filed by Johnson & Johnson Consumer Companies, Inc. ("Applicant"), the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a human drug product known by the tradename Vusion®, which was approved for commercial marketing and use by the Food and Drug Administration ("FDA") on February 16, 2006.

A determination has been made that the '932 patent is **NOT** eligible for patent term extension based upon the regulatory review period of Vusion®. Therefore, Applicant's PTE application is **DENIED**.

FACTUAL BACKGROUND

1) On March 27, 1990, the USPTO issued the '932 patent to Charles E. Clum and David M. Isaacson; it was originally assigned to Johnson & Johnson Baby Products Company, now Johnson & Johnson Consumer Companies, Inc.

2) On February 16, 2006, the FDA approved New Drug Application ("NDA") No. 21-026, thereby granting permission for commercial marketing or use of Vusion® (miconazole nitrate, zinc oxide, and white petrolatum).

3) On April 5, 2006, Applicant filed a PTE application under § 156 to extend the term of the '932 patent based on the FDA regulatory review period of Vusion®.

4) On September 7, 2006, pursuant to the Memorandum of Understanding Between the USPTO and the FDA, *see* 52 Fed. Reg. 17830, May 12, 1987, the USPTO requested assistance from the FDA ("First USPTO Letter to FDA") in determining eligibility of the '932 patent for patent term extension based on the regulatory review period of Vusion®. The USPTO indicated in its letter that "the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, [it] note[d] that miconazole nitrate has been previously approved under section 505(b) of the Federal Food Drug and Cosmetic Act

(21 U.S.C. 355(b)) and was approved for marketing and use in several products before the approval of Vusion™." Thus, the USPTO asked the FDA to "confirm the approval of Vusion™, i.e., the other active ingredients of Vusion™, were subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use."

5) On December 19, 2006, Applicant filed a Request for Interim Extension pursuant to the provisions in § 156(e)(2).

6) On March 20, 2007, the USPTO granted an interim extension based on the regulatory review period for Vusion®.

7) On March 29, 2007, the FDA responded to the First USPTO Letter to FDA. The FDA indicated that Vusion® was subject to a regulatory review period within the meaning of § 156(g) as required by § 156(a)(4). The FDA further indicated that two of the active ingredients in Vusion® (miconazole nitrate and zinc oxide) do not represent the first permitted commercial marketing or use of the product as defined under § 156(f)(1). The FDA indicated that it has no record that the third active ingredient of Vusion®, white petrolatum, had been previously approved under section 505 of the FFDCA as an active ingredient in a drug product, but that it had been previously approved for commercial marketing as an inactive ingredient in drug products reviewed and approved under section 505 of the FFDCA. Finally, the FDA indicated that the NDA was approved on February 16, 2006, and that the submission of the PTE Application on April 5, 2006, was timely within the meaning of § 156(d)(1).

8) On June 12, 2007, the USPTO sent a second letter to the FDA ("Second USPTO Letter to FDA") requesting that the FDA determine the applicable regulatory review period pursuant to § 156(d)(2)(A).

9) On November 26, 2007, Applicant filed a Second Request for Interim Extension pursuant to the provisions of § 156(e)(2).

10) On March 20, 2008, the USPTO granted a second interim extension based on the regulatory review period for Vusion®.

11) On July 9, 2008, the USPTO reconsidered their determination that Applicant could rely on the third active ingredient, white petrolatum, for eligibility for patent term extension and issued an Order to Show Cause. In that Order, the USPTO found that white petrolatum was the only active ingredient in Vusion® not previously granted permission for commercial marketing or use under section 505 of the FFDCA that could serve as the basis for extension under § 156. Nevertheless, the USPTO found that the '932 patent did not claim white petrolatum, rendering the '932 patent ineligible for extension.

12) On September 8, 2008, Applicant responded to the Order to Show Cause.

13) On February 23, 2009, Applicant filed a Third Request for Interim Extension pursuant to the provisions of § 156(e)(2).

DECISION

The USPTO has considered the arguments made by Applicant in its Response to the Order to Show Cause and finds each to be unpersuasive. The USPTO will address Applicant's arguments in turn.

I. The Regulatory Review of Zinc Oxide as an Active Ingredient in Previously Approved Products Occurred under the Same Provision of Law under which VUSION® Was Reviewed

Applicant admits that zinc oxide was previously approved under section 505 of the FFDCA, but argues that the approvals are not under the same "provision of law" because there was no requirement for efficacy prior to the Drug Amendments of 1962.[1] Response to Show Cause Order at 6-7. In essence, Applicant contends that each version of the same statutory provision constitutes its own "provision of law," *i.e.*, that one statutory provision becomes a different statutory provision, at least for purposes of § 156, upon amendment. Additionally, Applicant argues that *Westwood Pharmaceuticals Inc. v. Quigg*, 1989 WL 205631; 13 U.S.P.Q.2d 2067 (D.D.C. 1989), although directly on point, was wrongly decided and would not be decided the same today "in view of FDA's more recent indication of the criticality of efficacy when considering the approval of a drug for commercial marketing or use." Response to Show Cause Order at 4. Applicant also contends that *Westwood* is distinguishable because the drug in that case contained a single active ingredient whereas its drug Vusion® contains three active ingredients. *Id.* Applicant is mistaken on all scores.

The starting point for statutory interpretation is the language of the statute itself. Statutory words are normally presumed to be used in their ordinary and usual sense, absent evidence to the contrary. *Caminetti v. United States*, 242 U.S. 470, 485 (1917). Section 156(a)(5)(A) states that patent term extension is available if the approval at issue is "the first permitted commercial marketing or use of the product under the *provision of law* under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A) (emphasis added). Section 156(g) identifies the applicable provisions of law for each class of products for which patent term extension is available. It specifically identifies section 505 of the FFDCA, codified at 21 U.S.C. § 355, for new human

---

1 Pub. L. 87-781, 76 Stat. 780 (Oct. 1962). The Drug Amendment of 1962 amended section 505(b) of the FFDCA by inserting, immediately after the words "is safe for use", the words "and whether such drug is effective in use." The Drug Amendment of 1962 also amended section 505(d) to require that there be substantial evidence that the drug have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

drugs. That section has been the applicable provision of law under which drug products have been approved for commercial marketing or use since 1938. Nowhere does section 156 state or imply that amending any one of the identified statutory provisions renders it a new provision of law under which a patent term extension could be granted for a product that has already undergone regulatory review. Nor does Applicant point to any such statutory language. Thus, § 156 is clear on its face that the phrase "provision of law" means the statutory authority under which regulatory review occurs for a specific class of products, including any amendments to that statutory authority.

The legislative history supports the USPTO's interpretation of § 156. Congress gave no indication during the promulgation of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") that it intended to create a new opportunity for patent term extension on the basis of an amendment, even a significant one, of the federal statute governing regulatory review of a new drug product. Instead, the legislative history reveals that Congress was concerned that eligibility for patent term extension be limited to products that had been approved for the first time by the FDA, except in one instance specifically identified. According to a report by the House Committee on Energy and Commerce, accompanying H.R. 3605:

> Paragraphs (6) and (7)[2] describe two conditions which must be met by the product which is claimed in the product patent to be extended, or the use or manufacture of which is claimed in the use or process patent to be extended. First, the product must have been subjected to a regulatory review period under an applicable federal law, and approved, before the product was allowed to be commercially marketed. (The product which can be the subject of a patent extension is hereinafter referred to as the "approved product.") Second, with one exception, the approved product must have been approved for commercial marketing for the first time. The exception involves an approved product made under a patented process which primarily uses recombinant DNA technology. Such an approved product could have received its second approval for commercial marketing, but it must be the first time a product made by the claimed process has been approved.

H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Part 1, 37-38 (1984), reprinted in 1984 U.S.C.C.A.N. 2670-1. This excerpt is significant for two reasons. First, there is a clear expression of Congressional intent to limit eligibility to the first approval of a product for commercial marketing. Specifically, eligibility was intended to be limited to a drug product that had been approved by the FDA for the first time. Second, Congress set forth only one exception to the general requirement that eligibility be based on the first approval. That exception was for products made from recombinant DNA. When Congress enumerates certain exceptions to a general prohibition, other exceptions are not to be implied absent contrary legislative intent. *Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616-7 (1980).

Additionally, Congress was aware of the differences between the approval process for new drugs before 1962 and the approval process after 1962. According to the House report discussed

---

2 Paragraphs (6) and (7) in this excerpt correspond to paragraphs (5)(A) and (5)(B) in § 156(a) as enacted.

earlier:

> Prior to 1962, the Federal Food, Drug and Cosmetic Act (FFDCA) required that all drugs be approved as safe before they could be marketed. The 1962 amendments required that all new drugs, generic and pioneer, must be approved as safe and effective prior to marketing.
>
> As a result of the 1962 amendments, FDA did two things regarding pre-1962 drugs. First, the agency created the Drug Efficacy Study (DESI) to determine if all pre-1962 drugs were effective. Second, FDA established a policy permitting the approval of a generic drug equivalent to a safe and effective pre-1962 pioneer drug.

H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Part 1, 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2649. Despite its awareness, Congress did not make or even mention any distinction between drugs approved before or after 1962 in enacting the patent term extension provisions of Title II of the Hatch-Waxman Act. By contrast, Congress stated that its purpose for Title I of the Hatch-Waxman Act was to change the approval process for generic drugs approved after 1962 as indicated from the same House report:

> The purpose of Title I of the bill is to make available more lost cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. Under current law, there is a generic drug approval procedure for pioneer drugs approved before 1962, but not for pioneer drugs approved after 1962.
>
> Title I of the bill generally extends the procedures used to approve generic copies of pre-1962 drugs to post-1962 drugs. Generic copies of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing.

Id. at 2647-48. Thus, Congress presumably did not intend new drugs approved before 1962 to be treated differently from new drugs approved after 1962 for the purposes of eligibility for patent term extension under Title II. Had Congress intended to so do, it demonstrated via its alteration of the procedures for approval of a generic drug in Title I that it was capable of selecting words to affect a difference.

Case law likewise supports the USPTO's interpretation of § 156. In *Westwood,* the D.C. District Court addressed Applicant's argument here, *i.e.*, whether an amendment of section 505 of the FFDCA results in a new provision of law under which patent term extension becomes available again for an active ingredient originally approved before the amendment and then approved again after the amendment, and agreed with the USPTO's interpretation. More specifically, the applicant in *Westwood* obtained FDA approval for its drug having lactic acid as the active ingredient pursuant to Section 505 of the FFDCA and sought a patent term extension. *Westwood,* 13 USPQ 2d at 2068. The USPTO denied the extension on the ground that the *Westwood* applicant's drug was not the first permitted commercial marketing or use of lactic acid under the provision of law under which regulatory review occurred in light of the FDA's earlier approval of eight other drug product under Section 505 of the FFDCA containing lactic acid. *Id.* at 2069. In

challenging the USPTO's denial, the *Westwood* applicant argued that (i) section 505 of the FFDCA was amended by the Drug Amendments of 1962 incorporating effectiveness as a pre-condition for drug approval, rendering it a new provision of law from the pre-1962 version; and (ii) that its product was the first one approved under the effectiveness standard set forth in the 1962 amendments. *Id.* The court rejected the *Westwood* applicant's arguments, agreeing instead with the USPTO that an amendment does not produce a new provision of law for purposes of patent term extension eligibility. *Id.* It found that the agency's interpretation "is consistent with the statutory language and with the legislative history associated with this provision." *Id.* at 2068-69. Hence, the court deferred to the agency's interpretation. *Id.*

Applicant's attempt to circumvent *Westwood* on the grounds that it was wrongly decided then and that it would be decided differently today lacks merit. *Westwood* remains good law; it has not been overturned by the D.C. Circuit or Supreme Court. Nor has any court given any indication, even in *dicta*, that it would reach a different statutory interpretation for the meaning of "provision of law" than the *Westwood* court. Additionally, Applicant's factual distinction of *Westwood* is irrelevant. The D.C. District Court did not base its decision on the number of active ingredients in the drug product. Rather, the court based its decision on the construction of § 156 and its legislative history. *See id.* at 2069.

Taking the plain meaning of § 156 together with its legislative history and *Westwood*, the agency's interpretation of the statutory phrase "provision of law" means that the 1962 Drug Amendments to section 505 of the FFDCA did not result in a new provision of law, regardless of how that amendment changed the requirements of section 505. The pre-1962 version and the post-1962 version are but one "provision of law." A product approved for commercial marketing or use under the pre-1962 version cannot support a patent term extension later in time if given FDA approval for a different indication under the post-1962 version. Hence, the FDA's recent approval of zinc oxide under Section 505 of the FFDCA in Applicant's Vusion® drug product does not support the extension of the '932 patent since the FDA previously approved that compound under Section 505 of the FFDCA as an active ingredient in connection with a different drug product.[3]

II. The Plain Language of § 156(f) Requires that the USPTO Apply the Definition of Product in a Multi-Active Ingredient Drug Product to Each Individual Component of that Product

Applicant argues that Vusion® contains three active ingredients (zinc oxide, miconazole nitrate, and white petrolatum) that physically function together as a single indivisible entity. Response to Show Cause Order at 9-11. As such, Applicant asserts that *Arnold Partnership* is not applicable to the facts here. Applicant is mistaken; that case is directly on point to the present eligibility determination.

---

3 Furthermore, in establishing two monographs for Over the Counter (OTC) products, one for skin protectant drug products and one for anorectal drug products, FDA evaluated information regarding the safety and effectiveness of zinc oxide in the two drug products subject to the two OTC monographs. *See* Skin Protectant Drug Products For Over-the –Counter Human Use, Establishment of a Monograph; Notice of Proposed Rulemaking, 43 Fed. Reg. 34628, 34641 (Aug. 4, 1978) and Anorectal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph, Proposed Rule, 45 Fed. Reg. 35576, 35635 (May 27, 1980). Copies attached hereto.

In *Arnold Partnership*, the applicant sought a patent term extension based upon the FDA approval of a product consisting of two active ingredients. The USPTO denied the extension on the grounds that both active ingredients had been previously marketed either alone or in combination with other active ingredients. The Federal Circuit affirmed the denial, interpreting § 156 to require eligibility determinations to be made on an ingredient-by-ingredient basis. *Arnold Partnership*, 362 F.3d at 1341. The Federal Circuit explained: "To extend the term of a patent claiming a composition comprising A and B, either A or B must not have been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product." *Id.* Additionally, the Federal Circuit specifically rejected the argument that Applicant makes here, *i.e.*, that "the patent for combination drug product AB could receive an extension because the combination has not received prior approval, even though drug product A and drug product B have separate, prior approvals." *Id.* at 1342.

Because the two claimed active ingredients in Vusion®, zinc oxide and miconazole nitrate, have each been previously approved for commercial marketing or use under Section 505 of the FFDCA, Applicant fails to meet the eligibility requirement of § 156(a)(5)(A) under *Arnold Partnership* and thus its '932 patent is ineligible for a patent term extension.

III. Claim Construction of "Skin Care Composition" Does Not Inherently Require White Petrolatum

Applicant admits that white petrolatum is not explicitly recited in the claims of the '932 patent, but asserts that it is inherently included via the phrase "skin care composition," which appears in claim 1 and 2. Response to Show Cause Order at 11. Applicant's argument is unavailing. The skin care composition of claims 1 and 2 only require miconazole nitrate and zinc oxide. Those claims recite:

> 1. A skin care composition comprising as the active components (a) miconazole nitrate of the formula * * * and (b) zinc oxide; wherein the miconazole nitrate and zinc oxide are present in a ration of from about 1:60 to about 1:333.
>
> 2. The composition of claim 1 wherein the miconazole nitrate and zinc oxide are present in a ratio of about 1:60.

'932 patent, col. 8, ll. 24-44.

While the "comprising" transition phrase found in claim 1 leaves open the possibility that the skin care composition could contain additional components, there is nothing to suggest that it necessarily will do so. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (explaining that "comprising" is a term of art used in claim language to indicate that the named elements are essential, but that other elements may be added and still form a construct within the scope of the claim). Likewise, there is nothing to suggest that if the skin care composition of claim 1. contains an additional component that it will necessarily be white petrolatum. Further, that Examples IV and V in the specification list white petrolatum as a component in the skin care composition does not mean that claims 1 and 2 necessarily include that compound, contrary to

Applicant's argument. *See* Response to Show Cause Order at 11-13. Accordingly, because the '932 patent does not expressly claim white petrolatum and because the skin care composition of claims 1 and 2 does not necessarily require that compound, the USPTO finds that the '932 patent fails to satisfy the eligibility requirement of § 156(a), which provides the patent subject to extension must claim the product. *See* 35 U.S.C. § 156(a) (preamble).

IV. Vacatur of Interim Extensions Previously Granted under § 156(e)(2)

Applicant requests clarification with respect to the vacatur of the two earlier-granted interim extensions. Specifically, Applicant asserts that MPEP § 2775.01, cited in the Order to Show Cause, does not state that an interim extension *must* be vacated *ab initio*, but instead states that "where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension *may* be vacated *ab initio.*" Response to Show Cause Order at 13 (emphasis added). Applicant also argues that Vusion® was granted three years of new product marketing exclusivity by the FDA and, as such, that there is no actual impact on the public until that exclusivity ends on February 16, 2009. *Id.* at 13-14.

With respect to the first point, the Office has reconsidered its position taken in the Order to Show Cause regarding vacatur of the two previous interim extensions granted to Applicant under § 156(e)(2). When the Office issued the two previous interim extensions, the Office determined at the time that the '932 patent was eligible for a patent term extension. As a result, the Office will not vacate the first previously-granted interim or the portion of the second previously-granted interim extension from March 27, 2008, to the date of this decision. However, since the Office has determined that the '932 patent is ineligible for a patent term extension, *see supra* § I-III, the Office vacates the portion of the second previously-granted interim extension covering the period from the date of this decision to March 27, 2009. Lastly, the Office notes that Applicant is correct that the MPEP § 2775.01 contains permissive "may" language rather than mandatory "must" language concerning the vacatur of an interim extension granted in error.

With respect to the second point, the protection afforded by new drug product marketing exclusivity is separate and distinct from patent protection. Accordingly, the expiration of the FDA exclusivity period is irrelevant to the propriety of a previously-granted interim extension under § 156(e)(2).

V. Applicant's Pending Third Interim Extension Request Is Denied

Applicant filed a third interim extension application to extend the term of the '932 patent for another year because the '932 patent is due to expire on March 27, 2009. Section 156(e)(2) provides for an interim patent term extension while an applicant's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire *before a certificate of extension is issued or denied* under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year *if he*

determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. *See Somerset Pharms., Inc. v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '932 patent will not expire before a certificate of extension is issued or denied since the Director is herein denying Applicant's PTE application. *See infra*, § I-III. The second requirement is not met because the Director herein is issuing a negative eligibility determination, thus divesting him of authority to grant an interim extension. *Id.; see Somerset*, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); *see also In re Alcon Labs. Inc.*, 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for extension). Accordingly, since neither requirement for a interim extension under § 156(e)(2) is satisfied, the Office must deny Applicant's pending third interim extension request.

CONCLUSION

Applicant's PTE application is **DENIED**. The Office is **VACATING** the term of the second previously-granted interim extension from the date of this decision through March 27, 2009. Furthermore, Applicant's Third Request for Interim Extension is also **DENIED**.

THIS IS CONSIDERED A FINAL AGENCY DECISION.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Robert A Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: VUSION®
FDA Docket No.: 2007E-0035